

EXHIBIT B

Janet Tomezsko, M.D.

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON
4 IN RE: ETHICON, INC., Master File No.
5 PELVIC REPAIR SYSTEM 2:12-MD-02327
6 PRODUCTS LIABILITY MDL No. 2327
LITIGATION Joseph R. Goodwin
U.S. District Judge

THIS DOCUMENT RELATES
7 TO:
All Wave II TVT Cases
8 Jean Fleck v. Ethicon,
Inc., et al.
9 Case No. 2:12-cv-01681
10 Phyllis Martin v.
Ethicon, Inc., et al.
11 Case No. 2:12-cv-02029
12 Ramona Phillips v
Ethicon, Inc., et al.
13 Case No. 2:12-cv-02143
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14  
15 VIDEOTAPED DEPOSITION OF  
16 JANET TOMEZSKO, M.D.  
17 June 27, 2016  
18 8:07 a.m.  
19 9599 Skokie Boulevard  
20 Skokie, Illinois  
21  
22

23 Deanna Amore, CSR, RPR, 084-003999  
24

Janet Tomezsko, M.D.

1 they -- I believe they define erosion as a  
2 separation over the mesh versus extrusion is the  
3 mesh going into a cavity.

4 Q. Okay. So, fair to say, in practice, there  
5 is a difference?

6 A. Yes, there is.

7 Q. Doctor, do you believe the implantation of  
8 a TVT Retropubic can result in chronic  
9 inflammation?

10 MR. SNELL: Objection. Asked and answered.

11 BY MR. JACKSON:

12 Q. Doctor, I asked about chronic foreign body  
13 response before. I'm just asking about chronic  
14 inflammation now. Do you understand the question?

15 A. I believe I do.

16 So I don't believe that the TVT device  
17 will develop into a chronic inflammation that has a  
18 clinical effect.

19 Q. Okay. Doctor, I'm not asking about a  
20 clinical effect. Let me ask a better question.

21 Are you aware of any peer-reviewed  
22 literature that suggests that the type of  
23 polypropylene mesh contained in the TVT Retropubic  
24 device can result in chronic inflammation, whether

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1     you agree with that or not?

2           A.     Again, I look at the literature for what  
3     it proves, not what it suggests. So when you say  
4     am I aware of the "suggests," I really look at the  
5     literature for what is proven, and the literature  
6     does not show any chronic inflammation in the  
7     Level 1 evidence.

8           Q.     Are you aware of any literature that  
9     suggests that the type of polypropylene mesh used  
10    in the TVT Retropubic can cause chronic  
11    inflammation? Are you at least aware of that  
12    literature?

13          MR. SNELL: Object to form. Asked and  
14    answered.

15          THE WITNESS: I would guess there is something  
16    out there, and you can show it to me specifically,  
17    if there is something you want me to specifically  
18    look at.

19    BY MR. JACKSON:

20          Q.     Okay. Doctor, if there is literature out  
21    there that would show that there is a chronic  
22    inflammation associated with the implantation of  
23    the TVT Retropubic device, is it fair to say you  
24    disagree with that literature?

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1     Cochrane review to support your opinion in your  
2     report that the TVT Retropubic device is safe and  
3     effective?

4             A.     Yes.

5             Q.     You do.

6                     And is there a specific year of the  
7     Cochrane review that you are relying on?

8             A.     There are several years the Cochrane  
9     review has come out, and the most recent year is  
10    2015.

11            Q.     And sitting here, do you know whether the  
12    2015 Cochrane review specifically uses chronic,  
13    long-term pain as an end point?

14            A.     Again, I have -- I would have to look at  
15    the document to look for pain and the definition of  
16    pain.

17            Q.     But sitting here right now, is it fair to  
18    say you're not sure?

19            A.     Correct. I'm not sure. I'd have to look  
20    at the document.

21            Q.     Doctor, is there a randomized clinical  
22    trial anywhere for polypropylene mesh to treat  
23    stress urinary incontinence that tracks safety as  
24    the primary end point?

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1           A.    Most of the studies, the primary  
2    end points are efficacy, and secondary end points  
3    are safety.

4           Q.    So do you know of anywhere that's  
5    reversed, where safety is the primary end point?

6           A.    I do not, off the top of my head, no.

7           Q.    Okay. Doctor, are there any studies that  
8    you believe support your opinion that the  
9    TVT Retropubic device is safe and effective that  
10   specifically track dyspareunia as an end point?

11          A.    As a primary end point or the secondary  
12   end point?

13          Q.    Let's start with the primary end point.

14          A.    Not that I believe for a primary  
15   end point.

16          Q.    And how about as a secondary end point?

17          A.    It's usually tracked as a portion of the  
18   data, but I don't believe they are tracked as a  
19   secondary end point either, as a specific secondary  
20   end point.

21          Q.    So, Doctor, just to be clear, you don't  
22   believe there are any studies that support your  
23   opinion that the TVT Retropubic device is safe and  
24   effective that track dyspareunia as either a

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1 primary or secondary end point, correct?

2 A. I'm sorry. I believe you asked me if it  
3 was a randomized controlled trial. I'm sorry.  
4 Maybe I misunderstood.

5 Q. I think I was asking about just any  
6 studies. So let me back up.

7 Are there any studies that you know of  
8 that support your opinion that the TVT Retropubic  
9 device is safe and effective that track dyspareunia  
10 as a primary end point?

11 A. So the primary end points are usually done  
12 in randomized controlled trials.

13 So the meta-analysis and the Cochrane  
14 Reviews are looking at all the points, not just the  
15 primary or secondary end point.

16 So in terms of the best literature,  
17 Level 1 literature, looking at the end points of  
18 dyspareunia or pain, those are the best sources  
19 because they put together the most literature.

20 In a smaller, randomized, controlled  
21 trial, dyspareunia or chronic pain are not usually  
22 a secondary or primary end point because the rate  
23 is so low, you'd need just thousands of patients to  
24 use as a secondary or primary end point.

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1           So the best literature to look at is the  
2 meta-analysis and the Cochrane Reviews because they  
3 pull -- they pull all the literature, and then they  
4 can look at those, and at that point they are not  
5 called primary or secondary end points. They are  
6 just part of what they are looking at.

7           Q. Let me ask a very simple question, and  
8 I think we can move on.

9           Are there any studies that you believe  
10 support your opinion that the TVT Retropubic device  
11 is safe and effective that specifically track  
12 dyspareunia as a primary end point?

13          MR. SNELL: Object to form. Asked and  
14 answered.

15 BY MR. JACKSON:

16          Q. I'm just looking for a yes or no.

17          A. So yes.

18          Q. What studies?

19          A. I believe, as I just explained, that the  
20 Cochrane Reviews in the meta-analysis that use them  
21 as an end point in their research, that those  
22 studies support that.

23          Q. Okay. And it's your testimony that the  
24 2015 Cochrane review specifically tracks



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1 recently removed one.

2 Q. A partner you currently --

3 A. Work with, yes.

4 Q. -- work with recently removed an entire  
5 TVT Retropubic device?

6 A. Well, I'm sorry. I should clarify that.  
7 I'm not sure she was certain it was a TVT, but it  
8 was a retropubic sling. Sorry. It may not have  
9 been a TVT.

10 Q. Okay. So --

11 A. But for the technique of removing an  
12 entire retropubic sling.

13 Q. And I'm certainly not trying to violate  
14 anyone's privacy or anything, but, Doctor, let me  
15 try to ask a simple question here. Sitting here  
16 today, do you personally know of anyone who has  
17 removed an entire TVT Retropubic device?

18 A. So beyond the records that I have reviewed  
19 where they might have stated that they've removed  
20 an entire device, I know of people who removed --  
21 have removed entire retropubic slings, and I'm just  
22 not sure if they were TVT slings or not.

23 Q. So is it fair to say that sitting here  
24 today, you can't say that you have -- you can't say

Janet Tomezsko, M.D.

1 dyspareunia as a primary end point?

2 A. So, again, not using the word "primary end  
3 point." They don't use primary end point. They  
4 look at categories.

5 Q. Doctor, would you agree with me that one  
6 or more revision surgeries may be necessary to  
7 treat adverse reactions after the implantation of a  
8 TVT Retropubic device?

9 A. Yes.

10 Q. Doctor, do you believe that the entire TVT  
11 Retropubic device can be removed after it's ingrown  
12 into a woman's tissues?

13 A. I believe that you can attempt to remove  
14 the entire device, and I'm not sure, on a  
15 microscopic level, that you can remove the entire  
16 device.

17 Q. Okay. Doctor, have you personally  
18 performed TVT removal surgeries yourself?

19 A. Yes, I have.

20 Q. About how many?

21 A. Do you mean -- can you clarify what kind  
22 of removal?

23 Q. Doctor, have you ever personally removed  
24 an entire TVT device yourself?

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1           A.    I have never had a case where I needed to  
2   remove an entire TVT.  I've had to remove a large  
3   portion of it.

4           Q.    So fair to say you've never removed an  
5   entire TVT device yourself?

6           A.    Correct.  I've never been in a situation  
7   where I've needed to.

8           Q.    Okay.  Do you know anybody who has --

9           A.    Yes.

10          Q.    -- removed an entire TVT device yourself?

11          A.    Sorry.  Yes, I have.

12          Q.    And who would that be?  Do you know?

13          A.    Is that privileged information?

14          Q.    I mean, I'm -- I'm asking for -- do you  
15   know the name of a surgeon who -- who's removed an  
16   entire TVT device?

17          A.    Yes, I do.

18          Q.    Okay.  And can you tell me who that is?

19          A.    Wouldn't -- I'm concerned about privileged  
20   information because those are done so rarely that  
21   by naming that physician, it could easily lead to  
22   the patient identification because it's so rare  
23   that it's done, but, yes, I do.

24                I will tell you one of my partners

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1 recently removed one.

2 Q. A partner you currently --

3 A. Work with, yes.

4 Q. -- work with recently removed an entire  
5 TVT Retropubic device?

6 A. Well, I'm sorry. I should clarify that.  
7 I'm not sure she was certain it was a TVT, but it  
8 was a retropubic sling. Sorry. It may not have  
9 been a TVT.

10 Q. Okay. So --

11 A. But for the technique of removing an  
12 entire retropubic sling.

13 Q. And I'm certainly not trying to violate  
14 anyone's privacy or anything, but, Doctor, let me  
15 try to ask a simple question here. Sitting here  
16 today, do you personally know of anyone who has  
17 removed an entire TVT Retropubic device?

18 A. So beyond the records that I have reviewed  
19 where they might have stated that they've removed  
20 an entire device, I know of people who removed --  
21 have removed entire retropubic slings, and I'm just  
22 not sure if they were TVT slings or not.

23 Q. So is it fair to say that sitting here  
24 today, you can't say that you have -- you can't say

Janet Tomezsko, M.D.

1 you know of someone who has removed an entire TVT  
2 Retropubic device; is that fair?

3 A. No, because I do know of people who have  
4 removed them as part of the record, of patient  
5 records as part of the cases.

6 Q. And is that from the literature?

7 A. No, patient cases.

8 Q. Okay. Doctor, would you agree that  
9 removing an entire TVT Retropubic device may  
10 require aggressive dissection?

11 A. Yes, I would.

12 Q. And, Doctor, would you agree that there is  
13 no guarantee a surgeon would be able to remove an  
14 entire TVT device in the event it needed to be  
15 removed?

16 MR. SNELL: Form.

17 THE WITNESS: I agree.

18 BY MR. JACKSON:

19 Q. Doctor, would you agree that -- let me  
20 back up.

21 Doctor, you said you've personally  
22 performed revision surgeries on TVT Retropubic  
23 devices; is that correct?

24 A. I have performed revision surgeries on TVT

Janet Tomezsko, M.D.

1 BY MR. JACKSON:

2 Q. Doctor, do you believe that the TVT  
3 Retropubic device can curl and rope under tension?

4 A. I believe that with significant tension,  
5 it can curl or rope.

6 Q. Doctor, if there were Ethicon documents to  
7 the effect that the TVT Retropubic mesh could curl  
8 and rope, would you want to see those documents?

9 MR. SNELL: Object. Foundation.  
10 It assumes she hasn't.

11 THE WITNESS: As a -- just as an implanting  
12 clinician, do you mean, as opposed to an expert?

13 BY MR. JACKSON:

14 Q. Yes.

15 A. As an implanting physician, I -- we know  
16 all materials can change shape with the wrong use.  
17 So it's one of those common knowledge. So I don't  
18 need to see any internal materials to know that  
19 I can -- you know, I can ruin a suture by tying it  
20 wrong. I can ruin an implant by positioning it  
21 wrong. So I don't think it's really necessary to  
22 see them because it's part of the common knowledge  
23 of procedures that you do have to use the device or  
24 position it correctly.

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1 Q. And, Doctor, you believe that the  
2 2015 Cochrane review supports your opinion that the  
3 TVT Retropubic device is safe and effective,  
4 correct?

5 A. Yes.

6 Q. Okay. And I believe we stated earlier  
7 that the Cochrane review -- I'm sorry. Strike  
8 that.

9 The Cochrane review is a meta-analysis of  
10 different studies, correct?

11 A. Yes, it is.

12 Q. Okay. And those different studies --  
13 I'm sorry. Strike that.

14 The Cochrane review that you cite in your  
15 report that cites to different studies and looks at  
16 different studies includes various midurethral  
17 slings, correct?

18 A. That is correct. It does include varied  
19 midurethral slings, but it's heavily weighted upon  
20 the TVT data. The vast majority of the data that's  
21 used is the TVT Retropubic.

22 Q. Okay. And there is also data from other  
23 devices from other manufacturers in the  
24 2015 Cochrane review that you rely on, correct?

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1 A. Yes, there is.

2 Q. And so, for example, are you relying on  
3 data on the SPARC and other midurethral slings to  
4 support your opinion that the TVT Retropubic device  
5 is safe and effective?

6 A. Well, since I'm relying on data from  
7 multiple different studies, not just the Cochrane  
8 review, that is part of the Cochrane review but,  
9 again, the vast percentage of all the literature  
10 I'm looking at is TVT Retropubic-based.

11 Q. But would you agree with me you're looking  
12 on -- looking at some literature that relies on the  
13 SPARC, for example, and other midurethral slings to  
14 support your opinion that the TVT Retropubic device  
15 is safe and effective?

16 A. Yes.

17 Q. Okay. So what makes you say the  
18 TVT Retropubic device is safe and effective based  
19 on a different product?

20 MR. SNELL: Object. Form.

21 Go ahead.

22 THE WITNESS: So I'm not doing it based on a  
23 different product, and actually, the Cochrane  
24 review says the retropubic top-down approach, the



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1 SPARC, is not included as part of their retropubic.  
2 They're talking about midurethral slings that are  
3 top-up approach. So -- and so the vast majority of  
4 the data -- when you look at the other studies --  
5 the Schimpf, Tommaselli -- they are primarily  
6 TVT Retropubic studies. So I can say with  
7 confidence that this is, you know, this is TVT  
8 Retropubic data primarily.

9 BY MR. JACKSON:

10 Q. And what other top-up products are  
11 included in the 2015 Cochrane review other than the  
12 TVT Retropubic device?

13 A. That's the vast majority. I can --

14 MR. SNELL: Counsel, I think you said top-up  
15 instead of bottom-up --

16 MR. JACKSON: Oh, I'm sorry. Thank you.

17 MR. SNELL: -- unless I misheard.

18 THE WITNESS: He did, but I might have said it  
19 too.

20 BY MR. JACKSON:

21 Q. What other bottom-up slings are included  
22 in the 2015 Cochrane review other than the  
23 TVT Retropubic device?

24 A. Can I look that up for you? Can I --

Janet Tomezsko, M.D.

1 Q. Certainly.

2 A. -- bring it up for you?

3 Do we need to go off the record while I  
4 find it?

5 MR. JACKSON: Sure. Let's go off the record.

6 THE VIDEOGRAPHER: The time is 10:57 a.m., and  
7 we are going off the video record.

8 (Brief interruption.)

9 THE VIDEOGRAPHER: The time is 11:03 a.m., and  
10 we are back on video record.

11 BY MR. JACKSON:

12 Q. Doctor, before we went off the record,  
13 I asked you what other bottom-up slings, other than  
14 the TVT Retropubic device, are included in the  
15 2015 Cochrane review. We've taken a few moments  
16 off the record for you to review that 2015 Cochrane  
17 review.

18 Are you able to answer that question?

19 A. Yes, so looking through their list, the  
20 vast majority of the retropubic-type bottom-up is  
21 TVT. There is Vypro, ULTRAPRO, Prolene light mesh,  
22 and the Okulu study, just going through them --  
23 they are -- there is an occasion one that just says  
24 retropubic, the IV-- IVS similar system, but the

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1 vast majority are TVT retropubic, you know, that  
2 are not SPARC or transobturator.

3 Q. So, Doctor, you listed the IVS, the  
4 ULTRAPRO, the Vypro?

5 A. Correct.

6 Q. And those are all bottom-up midurethral  
7 slings listed in the 2015 Cochrane review?

8 A. Correct.

9 There is -- I found -- so there is one  
10 study with an ULTRAPRO Vypro, and then there is one  
11 study with ObTape and DUPS, which I'm not sure  
12 exactly what that is. I'd have to look that up.

13 And there is another one that just says  
14 retropubic. So I'm not sure which study that is.  
15 I'd have to look that up. There is some  
16 nonspecific language in this summary table that I'm  
17 looking at.

18 Q. And, Doctor, when you see a study that  
19 just said "retropubic" and doesn't specify a  
20 particular product, do you find that study to  
21 reliably inform your opinion on whether the  
22 TVT Retropubic device is safe and effective?

23 A. So that study --

24 Q. Doctor, I'm just asking generally. I'm

Janet Tomezsko, M.D.

1 not asking about a specific study.

2 MR. SNELL: Object to speculation and vague on  
3 define.

4 THE WITNESS: Right.

5 So I would have to look at that specific  
6 document to know whether that's a TVT in itself,  
7 but assuming that it's not, since the vast majority  
8 of the studies, the vast majority of the patients  
9 looked at TVT Retropubic, I can reliably use this  
10 as a source for the TVT Retropubic.

11 BY MR. JACKSON:

12 Q. We can switch directions and move on.

13 Doctor, we talked a little bit earlier  
14 about the TVT Retropubic Instructions for Use; do  
15 you remember that?

16 A. Yes.

17 Q. Okay. And do you remember reading the  
18 testimony of an Ethicon employee named Meng Chen  
19 about the Instructions for Use of the TVT IFU?

20 A. Yes.

21 Q. And can you tell me, sitting here, what  
22 you remember about that testimony?

23 A. I believe -- again, I'm not good with the  
24 names but the substance of the IFUs -- I believe it